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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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11/19/2003

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| EXAMINER |
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THALER, MICHAEL H

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| ART UNIT | PAPER NUMBER |
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3731

DATE MAILED: 11/19/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/919,583

Applicant(s)

TRUWIT ET AL.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,9-13 and 17-35 is/are pending in the application.
- 4a) Of the above claim(s) 23-25,32 and 33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26-31,34 and 35 is/are allowed.
- 6) ☒ Claim(s) 1-5,9-13 and 17-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11</u> . | 6) <input type="checkbox"/> Other: _____ |

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Claims 1-5, 9-13 and 17-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no basis in the original disclosure for the limitation that the vibration is substantially independent from the introducer. The original disclosure is silent as to whether or not the introducer is vibrated to some extent by the vibration of wire 24. There is no basis in the original disclosure for the limitation that cutting occurs without using electric current for performing the cutting. The original disclosure nowhere indicates that the external device for producing ultrasonic energy (described on page 3, lines 23-25 of the specification) does not use electric current. There is no basis in the original disclosure for the limitation that wire 24 has a cutting "edge". Although the formed cutting surface of the blade (described on page 3, lines 26-27 of the specification) is an edge, the wire 24 is not disclosed as having an edge.

Claims 1-5, 9-13 and 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. The claims are confusing and inaccurate for the reasons set forth above. Therefore the scope of the claims is unclear. Further, in claim 17, lines 8-9, "the means for cutting entering the opening in the inner member" is not understood. Also, in line 9, it is unclear what form of movement "the means for cutting travels with respect to the opening in the inner member" is.

Claims 1, 2, 5, 9, 10, 13, 17, 18, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuris (3,565,062). Kuris, in figures 10-11, discloses cylindrical introducer member 76c, 75c having an opening (at the top of 75c) along a side, cutting edge 50c for cutting tissue entering the opening as it travels with respect to the opening (col. 6, lines 71-75 and col. 10, lines 49-52). The Kuris specification fails to specifically indicate that the vibration of the cutting edge is substantially independent from the introducer. However, it would have been obvious that this is the case since the ultrasonic generator is directly connected to the transmission member 42c and thus the cutting edge but it is not directly connected to introducer member 76c, 75c. As to claim 2, for example, the ultrasonic vibrations of Kuris inherently coagulate blood. As to claim 17, the Kuris embodiment of figures 10-11 fails to include a

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hollow core in inner member 42c or an opening along a side of the inner member 42c. However, Kuris, in the embodiment of figures 8 and 9, teaches that the inner member 42a or 42b should be hollow in order to remove cut particles and treatment fluid (col. 7, lines 64-66 and col. 10, lines 11-12). It would have been obvious to make the core of the inner member 42c of the figures 10-11 embodiment hollow so that it too would have this advantage. Also, Kuris, in the embodiment of figures 8 and 9, teaches that the inner member 42a or 42b should include an opening 54a or 54b along its side in order to permit proper mixing of fluid (col. 10, lines 36-38). It would have been obvious to include a side opening in the inner member 42c of the figures 10-11 embodiment so that it too would have this advantage.

Claims 3, 4, 11, 12, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuris (3,565,062) in view of Lecrone (4,685,458). Kuris fails to disclose a wire as the means for cutting. However, Lecrone teaches that a wire 51 is an alternative to a blade 62 as a means for effectively cutting blood vessel blockages. It would have been obvious to use a wire in place of the blade of Kuris for this reason.

Claims 26-31, 34 and 35 are allowed.

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's arguments with respect to claims 1-5, 9-13 and 17-22 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael


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Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703)872-9306 for regular communications and (703)872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
November 12, 2003


MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731